

Quality/Regulatory Orientation Guide



Quality/Regulatory Orientation Guide

INTRODUCTION

Today's health care environment requires many professionals to have a broad knowledge of the health care delivery system and processes. These individuals often are chosen for new positions or have areas of responsibility added to their current roles because they have demonstrated strong clinical or project management skills, although they may have limited experience in these areas. It is not uncommon for a quality or patient safety manager also to be involved in regulatory compliance and vice versa.

The Quality/Regulatory Orientation Guide is primarily designed for professionals who are new to their current position or new to the organization. The guide may be beneficial to experienced staff wanting to become more familiar with other staff members' roles, and the guide can help orientate quality, regulatory and patient safety employees to their roles. Communication and an understanding of the roles of other departments are vital to ensure quality outcomes, and patient and professional satisfaction.

REGULATORY COMPLIANCE



Potential Areas of Responsibility

- When was your last Medicare CoP and/or hospital licensure survey?
- Have you reviewed your most recent CMS survey results? (Review CMS Form 2567 "Plan of Correction/Statement of Deficiencies" for key areas of concern.)
- Who is charged with ensuring that these corrective action plans are being followed as written?
- Has the action plan been worked into your quality assurance and performance improvement program?
- Is there a process/committee to ensure ongoing survey readiness?
- What is your role in ensuring regulatory compliance?
- Can you locate and navigate the state health care regulations online?
- Who is responsible for compliance with life safety codes?
- Have you identified which state hospital and professional health care licensure rules apply to your hospital?
- Have you identified which CoPs appendices apply to your hospital?
- Can you locate and navigate the applicable CoP appendices in the [State Operations Manuals](#) online?
- Have you reviewed the regulatory toolkits and resources available on [MHA.net.com](#)?
- Who surveys your laboratory? When is the next survey?
- If your hospital has a home health agency, hospice, ASC, RHC or LTC facility, who is responsible for ensuring regulatory compliance?
- When surveyors arrive on-site, what is your organization's process?
- Do you know who to call at the Missouri DHSS and at the CMS regional office for questions/concerns?
- Has an assessment been done to ensure hospital policies and procedures are current and conform to state and federal regulations?
- Are you familiar with HIPAA laws and patient privacy protections? What is your role in ensuring compliance?
- Are you familiar with EMTALA laws? What is your role in ensuring compliance?

REGULATORY COMPLIANCE



Potential Areas of Responsibility

Helpful Hints

- Become familiar with the regulatory resources and toolkits located under the “Advocacy and Regulation” section of MHA’s website, MHAnet.com. Sign up for a password to have access to the password-protected resources, including regulatory self-assessment guides and state health care statutes and regulations. Sign up for MHA’s daily e-newsletter, *MHA Today*, for the latest regulatory news updates.
- Get to know your state and CMS regulators.
- Perform a self-assessment using the regulatory self-assessment guide available on MHAnet.com.

Key Resources and Links

- [Missouri DHSS Division of Regulation and Licensure Rules](#) (hospitals, including rehabilitation and psychiatric, home health agencies, ambulatory surgical centers, trauma centers) —
- [State Hospital and Ambulatory Surgical Center Laws Chapter 197](#)
- [Medicare CoPs](#) (Click on appropriate letter, A for acute care, W for critical access, etc. to view.) —
- [Medicare Survey and Certification Memos](#)
- CMS Region 7 Division of Survey and Certification Operations Kansas City Branch Manager — Sherrian Pater — 816/426-2011
- [Missouri DHSS Division of Regulation & Licensure](#) — Jeanne Serra — 573/751-8535
- [Missouri DHSS Section for Health Standards and Licensure](#) — Julie Cread — 573/526-1864
- [Missouri DHSS Bureau of Hospital Standards](#) — Donya Lowrie — 573/751-6303
- [Missouri DHSS Section for Disease Prevention](#) (Communicable Disease Reporting) — Kristie Campbell — 573/526-4780
- Missouri [State Board of Registration for Healing Arts](#) — Connie Clarkston — 573/751-0098
- Missouri [State Board of Pharmacy](#) — Kimberly Grinston — 573/751-0093
- Missouri [State Board of Nursing](#) — Lori Scheidt — 573/751-0681
- [Missouri Hospital Association](#) — Sharon Burnett — 573/893-3700, ext. 1304
- Beneficiary and Family-Centered Care (BFCC) QIO for Missouri is [KEPRO](#), 855/408-8557. BFCC QIOs perform the following reviews: quality of care, medical necessity, DRG, readmission and EMTALA reviews. They also handle beneficiary complaints, discharge appeals and immediate advocacy concerns.

ACCREDITATION



Potential Areas of Responsibility

- | | |
|--------------------------|--|
| <input type="checkbox"/> | Is your hospital and/or specific hospital services accredited? |
| <input type="checkbox"/> | Who is responsible for hospital accreditation? |
| <input type="checkbox"/> | What are the accrediting bodies (TJC, DNV, HFAP) that accredit your organization? |
| <input type="checkbox"/> | What programs or services have special certifications from accrediting bodies? |
| <input type="checkbox"/> | Who is responsible for maintaining these certifications? |
| <input type="checkbox"/> | When was the last survey(s)? |
| <input type="checkbox"/> | What were the results of the last survey? |
| <input type="checkbox"/> | Are there any outstanding corrective action plans that need to be completed? |
| <input type="checkbox"/> | When is the next anticipated survey? |
| <input type="checkbox"/> | Is there a process/committee to ensure ongoing readiness? |
| <input type="checkbox"/> | If your hospital has a freestanding ASC that is not licensed under your hospital license, what is the ASC's accrediting organization? (AAASC, AAAASF, AAACN) |
| <input type="checkbox"/> | Has your hospital had any sentinel events reported in recent years? |

Helpful Hints

- If your institution is accredited, it's important to know where you are in the cycle of unannounced surveys.
- Your hospital may have separate surveys for specific services or programs like laboratory, stroke, rehab, ECHO, sleep lab, etc. These are usually scheduled surveys, so you will have more advanced notice to prepare.
- If you are accredited by TJC, learn how to access and use the S3 reports on its website. These reports provide hints on potential problematic areas you may encounter in your next survey.
- Become familiar with all the accrediting standards, especially those related to quality.
- Locate the manual(s), either paper or online, and learn to navigate it.

Key Resources and Links

- [TJC](#)
- [DNV](#)
- [HFAP](#)

QUALITY IMPROVEMENT ACTIVITIES

<input checked="" type="checkbox"/> Potential Areas of Responsibility
<input type="checkbox"/> What hospital groups/teams are currently working on QI projects?
<input type="checkbox"/> For critical access hospitals, is your hospital participating in the MBQIP through the Missouri Office of Rural Health and MHA?
<input type="checkbox"/> Is your hospital participating in the HEN with MHA or with another HEN network?
<input type="checkbox"/> Is your hospital participating in an improvement project with Primaris, the state QIO?
<input type="checkbox"/> Is your hospital participating in an improvement project with the Center for Patient Safety?
<input type="checkbox"/> What is your role in these QI projects?
<input type="checkbox"/> Who is responsible for collecting and reporting the data for each improvement project/team?
<input type="checkbox"/> What model for improvement does your hospital use? (PDSA, Lean, Six Sigma, CQI, etc.)
<input type="checkbox"/> Are you responsible for any routine reports that are given to the hospital's board of directors or senior leadership team?
<input type="checkbox"/> Do you have an IRB to review biomedical and behavioral research? What is your role?
<input type="checkbox"/> If you are not familiar with these models, find out how you can get trained.

Helpful Hints

- Review recent meeting minutes from the QI committee or council and all subcommittees of the medical staff (P&T, surgery, OB, etc.) Review recent survey plans of correction and root cause analysis documents.
- Ideally, your role in quality improvement projects is the role of planner, communicator, or facilitator and providing data assistance. If your hospital has quality improvement teams, someone with content knowledge and operational responsibility for the outcome of the project should be leading the project.
- Ideally, all projects that require any change of physician behavior or practice should have physicians on the project team.
- Include senior leadership on major QI teams.
- Join professional associations such as the NAHQ and the MoAHQ.
- Seek certifications, such as CPHQ.
- If accredited by TJC, locate and review your annual quality plan, and review and update your hospital's list of quality improvement teams.

Key Resources and Links

- *The Team Handbook* by Peter Scholtes is an excellent resource for basic QI and team facilitation skills.
- *The Q Solutions: Essential Resources for the Healthcare Quality Professional* is a series of books

published by the National Association for Healthcare Quality on various topics of interest to quality and regulatory compliance staff.

- *The Janet A. Brown Healthcare Quality Handbook* is a professional resource and study guide often used by professionals preparing to take the *Certified Professional in Healthcare Quality* exam.
- Quality Innovation Network (QIN) QIOs for Missouri is [TME](#), 800/725-9216
- [IHI](#)
- [Missouri Office of Rural Health](#)
- [CPS](#)
- [Primaris](#)
- [MBQIP](#)
- [NAHQ](#)
- [MoAHQ](#)

PERFORMANCE MEASUREMENT



Potential Areas of Responsibility

CMS Measures

- Who is your [QualityNet](#) administrator? Who is their back up? What is your Hospital CCN number? Memorize this number.
- Who is your contact at [FMOAI](#), the QIO responsible for providing training and assistance with the hospital quality reporting program?
- Who are your core measure vendors? You may have more than one. There might be different vendors for the core measures and for HCAHPS.
- Do you know how to access data reports from each of your data vendors?
- Who internally is responsible for collecting, abstracting and reporting your CMS data?
- What structural, process, outcome and claims-based measures are reported to QualityNet and subsequently to publicly reported websites?
 - Who abstracts this data?
 - What training have they received to be abstracters?

NHSN Measures

- What HAI measures are required by CMS to be reported to NHSN for your hospital? What additional NHSN data is reported?
- Who collects and enters your infection-related measures into NHSN?

Joint Commission Measures

- Who is your ORYX vendor?
- What are the hospital's required core and/or noncore measures?
- Who internally is responsible?

Other Required Measures

- Meaningful Use/eMeasures
 - What data is reported to whom and how often?
 - What is your responsibility?
 - Do you have access and use these data reports?
 - How is this data disseminated and to whom?

Other Required Measures

- MHIRS
 - What data is reported to whom and how often?
 - What is your responsibility?

PERFORMANCE MEASUREMENT



Potential Areas of Responsibility

- Do you have access and use these data reports?
- How is this data disseminated and to whom?



Other Payers, Insurance Companies

- What data is reported to whom and how often?
- What is your responsibility?
- Do you have access and use these data reports?
- How is this data disseminated and to whom?

Internal Quality Measurement



- What additional data is being intermittently collected, reviewed and reported?
- How is the data disseminated and to whom?
- How often is the data reviewed?

Helpful Hints

- Insurance companies may embed requirements for quality data reporting and may use this data for payment incentives or penalties. Contract renewals should be examined carefully for these additions and negotiated before renewal whenever possible. Find out who can help you review contracts for this kind of language.
- Always have at least two people who have access to data reporting online portals and know how to enter the data.
- Ensure your hospital is reporting all applicable measures to MHIRS. Contact Bob Patterson at DHSS at 573/522-9610 or bob.patterson@health.mo.gov.
- Performance Measurement under Helpful Hint
- Florida Medical Quality Assurance, Inc. FMOAI is the national support contractor for the Hospital Inpatient Value, Incentives, and Quality Reporting, Outpatient Quality Reporting Outreach and Education Support Programs. FMOAI provides education and direct support for the Hospital Inpatient Quality Reporting, EHR Incentive Program for Eligible Hospitals and Critical Access Hospitals, Hospital Value-Based Purchasing, and Inpatient Psychiatric Facility Quality Reporting.

Key Resources and Links

Sites that Publicly Report Data

- [QualityNet](#)
- [CMS Hospital Compare](#)
- [Missouri Healthcare Infection Reporting System](#)
- [Focus On Hospitals](#)
- [Kansas City Quality Consortium](#)
- [Leapfrog Hospital Safety Score](#)
- [The Joint Commission](#)
- [WhyNotTheBest](#)
- [The Dartmouth Atlas of Health Care](#)
- [Healthgrades](#)
- [U.S. News America's Best Hospitals](#)
- [Consumer Reports Hospital Ratings](#)
- [FMOAI](#)
- [QualityNet Help Desk](#) – 866/288-8912

PAY FOR PERFORMANCE PROGRAMS

<input checked="" type="checkbox"/>	Potential Areas of Responsibility
<input type="checkbox"/>	Is your hospital subject to CMS' Hospital Value-Based Purchasing Program, Hospital Readmission Reduction Program and Hospital-Acquired Conditions Reduction Program? If yes, do you know your hospital's performance and, if applicable, payment adjustment?
<input type="checkbox"/>	Is your hospital subject to any other quality related P4P programs with commercial insurance carriers? If yes, do you know your hospital's performance on these P4P programs?

Helpful Hints

- Review your hospital's performance by using HIDI Analytic Advantage[®], a Web-based platform from the Hospital Industry Data Institute. For more information, contact hidi@mail.mhanet.com.
- If applicable, use a value-based purchasing calculator or work with finance to analyze financial implications.

Key Resources and Links

- [Stratis Health Understanding Value-Based Purchasing Fact Sheet](#)
- [Stratis Health Understanding Hospital Readmission Reduction Program Fact Sheet](#)
- [Stratis Health Understanding HAC Reduction Program Fact Sheet](#)
- [HIDI Analytic Advantage](#)

PATIENT SAFETY

<input checked="" type="checkbox"/>	Potential Areas of Responsibility
<input type="checkbox"/>	Who is the patient safety officer(s) or person responsible for patient safety?
<input type="checkbox"/>	Who are the members of the hospital safety committee?
<input type="checkbox"/>	Do you have other safety related committees? (medication safety, environmental safety, employee safety, infection control, etc.)
<input type="checkbox"/>	Are the TJC National Patient Safety Goals , including the elements of performance for each goal, updated each year?
<input type="checkbox"/>	Are you familiar with and has your hospital implemented the National Quality Forum-endorsed safe practices ?
<input type="checkbox"/>	Has your hospital completed an HSOPS ? <i>If so, when and what were the results?</i>
<input type="checkbox"/>	What organization serves as your AHRO-recognized Patient Safety Organization for the purposes of reporting patient safety events?
<input type="checkbox"/>	What is your hospital's process if a " never event " occurs? Who is responsible? What events do you report to DHSS, TJC and the PSO?
<input type="checkbox"/>	What model or training does your hospital use to improve teamwork and patient safety? (TeamSTEPPS , Crew Resource Management, CUSP)
<input type="checkbox"/>	Are you able to perform an RCA or FMEA?

Helpful Hints

- Even if your hospital is not TJC accredited, it should adhere to the National Patient Safety Goals. Because these goals are revised slightly each year, you should distribute and retrain staff each year.

Key Resources and Links

- [TJC National Patient Safety Goals](#)
- [Healthcare Services Group Risk Management & Patient Safety Team](#)
- [Center for Patient Safety](#)
- [AHRO Patient Safety Resources](#)
- [National Patient Safety Foundation](#)
- [TeamSTEPPS](#)
- [Crew Resource Management](#)
- [CUSP](#)

INFECTION CONTROL

<input checked="" type="checkbox"/>	Potential Areas of Responsibility
<input type="checkbox"/>	Who, if not you, is your designated infection control officer?
<input type="checkbox"/>	Who is responsible for reporting communicable diseases to the local or state health department?
<input type="checkbox"/>	Who is responsible for reporting data to NHSN and/or MHIRS?
<input type="checkbox"/>	How is IC data/events incorporated into the QAPI plan?
<input type="checkbox"/>	Who prepares IC reports and how are these disseminated throughout the organization?
<input type="checkbox"/>	Who is responsible for employee health?

Helpful Hints

- Join APIC and your local chapter. They are an excellent resources.
- If new to IC, attend the MHA Essentials for IC Conference held annually in September.
- IC is one of the most frequently cited areas for noncompliance. See CMS Form 2567 "Plan of Correction/Statement of Deficiencies" for key areas of concern.

Key Resources and Links

- [NHSN](#)
- [MHIRS](#)
- [CDC](#)
- [APIC](#)
- [DHSS Surveillance and Communicable Disease Reporting](#)
- [Infection Prevention Checklist For Outpatient Settings](#)

MEDICAL STAFF AND PEER REVIEW

<input checked="" type="checkbox"/> Potential Areas of Responsibility
<input type="checkbox"/> Are you involved with the orientation and/or annual training of new physicians/providers?
<input type="checkbox"/> What is the medical staff structure? Are some or all of the physicians employed by the hospital/system?
<input type="checkbox"/> Do you have any responsibility for quality in the physician clinics?
<input type="checkbox"/> Do you have any responsibility for the PQRI to CMS in your clinics?
<input type="checkbox"/> Are you responsible for providing physician quality data/reports on a regular basis? If yes, what data, format, schedule and to whom do you send reports?
<input type="checkbox"/> Who is responsible for credentialing?
<input type="checkbox"/> Does your facility have OPPE and FPPE scorecards? <ul style="list-style-type: none">• New providers — TJC Ongoing Professional Practice Evaluation (OPPE)• Existing providers — TJC Focused Professional Practice Evaluation (FPPE)
<input type="checkbox"/> Who is responsible for the peer review process? <ul style="list-style-type: none">• What types of events are reported?• What triggers a review?• Who does the reviews?• What is the process for conducting the reviews?• How are the outstanding reviews tracked?• What is the process for reporting the results?• Where are the final reviews filed?
<input type="checkbox"/> Are there any follow-up actions you are responsible for tracking?

Helpful Hints

- Add all recurring reports to your online calendar and email system's calendar to prompt you one to two weeks before the reports are due.

Key Resources and Links

- [Physician Quality Reporting Initiative](#)

PATIENT SATISFACTION AND CUSTOMER RELATIONS

<input checked="" type="checkbox"/> Potential Areas of Responsibility
<input type="checkbox"/> Do you evaluate patient satisfaction using HCAHPS or another internal or external satisfaction survey?
<input type="checkbox"/> Who is your vendor for HCAHPS?
<input type="checkbox"/> Which areas of your hospital are surveyed? (inpatient, home health, physician clinics, etc.)
<input type="checkbox"/> What departments are surveyed? How are departmental results displayed?
<input type="checkbox"/> Are you familiar with the questions asked in the satisfaction survey? How is the data disseminated throughout the institution? Does the hospital board of directors see the data?
<input type="checkbox"/> How does your hospital compare on HCAHPS with other hospitals on Hospital Compare?
<input type="checkbox"/> If your vendor processes survey comments for you, who accesses and views these for your organization?
<input type="checkbox"/> When is your next employee satisfaction survey? How are the results discussed with the participants? Are your volunteers surveyed?
<input type="checkbox"/> When is your next medical staff survey? Do you use a vendor?
<input type="checkbox"/> Who handles patient complaints?
<input type="checkbox"/> Are you familiar with the CMS CoP related to handling complaints and grievances?
<input type="checkbox"/> Do you have a system to record all patient complaints and compliments?
<input type="checkbox"/> Who prepares the follow-up letters after patient complaints and compliments?
<input type="checkbox"/> Is there a service recovery program for employees to address patient complaints at the moment of reporting?
<input type="checkbox"/> What is your customer service program? Who teaches it? How often is it refreshed?

Helpful Hints

- Consider the use of balanced scorecards or dashboards to display the data easily.
- HCAHPS is a federal law, and you cannot tamper with it. You are not allowed to survey your inpatients until the process is complete for that discharge. Become familiar with the entire process.
- When surveying employee satisfaction internally, consider all groups that care for patients in any setting.

Key Resources and Links

- [HCAHPS](#)
- [Hospital Compare](#)

RISK MANAGEMENT

<input checked="" type="checkbox"/>	Potential Areas of Responsibility
<input type="checkbox"/>	Who is your insurance carrier?
<input type="checkbox"/>	Who is your legal counsel?
<input type="checkbox"/>	Does your insurance carrier offer training sessions and education? Be sure to avail yourself to them.
<input type="checkbox"/>	When was your last facility risk assessment completed? What were the results?
<input type="checkbox"/>	Are there any outstanding issues that need to be addressed?
<input type="checkbox"/>	Do you know how to perform an RCA using an approved template? (e.g. TJC template)
<input type="checkbox"/>	Do you understand what constitutes a “sentinel event” and what your hospital’s process is for investigation, follow-up and reporting to accrediting body and/or DHSS?
<input type="checkbox"/>	What is your facility’s peer review process? (See Medical Staff Section 8a – f)
<input type="checkbox"/>	How does your facility report and track variances? <ul style="list-style-type: none">• Does your facility use an electronic variance reporting system?• Do you know which system is used and how to abstract data for reporting purpose?• Who is responsible for ensuring appropriate follow-up is done on significant events?• Are these incorporated into your QAPI program?

Helpful Hints

- Make sure to secure the peer review and other protected documents.
- Learn the Missouri statutes on discoverability of documents and protection, and attach the appropriate phrase to secure documents.
- Find the statute of limitations for keeping documents and evidence. Your attorney will advise you.
- Locate your insurance carrier’s website and contact information.
- Locate your risk management group’s website and contact information.
- Locate your legal counsel’s contact information.

Key Resources and Links

- [HSG](#)

HOSPITAL COMMITTEES



Potential Areas of Responsibility



Do you have responsibility for any of these possible committees, including creation of the agenda, meeting facilitation, minutes and/or participation as a committee member?

- Hospital Quality Committee
- Board Quality Committee
- Medical Staff Quality Committee
- Medical Executive Committee/Medical Staff Committee
- Credentials Committee
- Peer Review Committee
- Accreditation Committee
- Infection Control Committee
- Risk Management Committee
- Patient Safety Committee
- Utilization Review Committee
- Management Meeting
- Customer Service Committee
- Pharmacy and Therapeutics Committee
- Other Committees

Helpful Hints

- Add all recurring meetings to your online calendar or email system's calendar.
- If you are responsible for meeting preparation, set recurring reminders for two weeks in advance.
- Find out who chairs each committee.

APPENDIX

A

AAAASF	American Association for Accreditation of Ambulatory Surgery Facilities
AAACN	American Academy of Ambulatory Care Nursing
AAASC	American Association of Ambulatory Surgery Centers
AHRQ	Agency for Healthcare Research and Quality
APIC	Association for Professionals in Infection Control and Epidemiology Inc.
ASC	ambulatory surgical centers

B

BFCC	Beneficiary and Family-Centered Care
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C

CCN	CMS certification number
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CoP	Conditions of Participation
CPOE	Computerized physician order entry; computerized prescription order entry
CPHQ	Certified Professional in Healthcare Quality
CPS	Center for Patient Safety
CQI	Continuous Quality Improvement
CUSP	Comprehensive Unit-based Safety Program

D

DHSS	Department of Health and Senior Services
DNV	Det Norske Veritas

E

EMTALA	Emergency Medical Treatment and Active Labor Act
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F

FMEA	failure modes and effects analysis
FMQAI	Florida Medical Quality Assurance, Inc.
FPPE	focused professional practice evaluation

H

HAC	hospital-acquired condition
HAI	healthcare associated infections
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HEN	Hospital Engagement Network
HFAP	Healthcare Facilities Accreditation Program
HIDI	Hospital Industry Data Institute
HIPAA	Health Insurance Portability and Accountability Act of 1996
HSG	Healthcare Services Group
HSOPS	Hospital Survey on Patient Safety

I

IC infection control
IHI Institute for Healthcare Improvement
IRB institutional review board

K

KEPRO Keystone Peer Review Organization

L

LTC long-term care

M

MBQIP Medicare Beneficiary Quality Improvement Program
MHIRS Missouri Healthcare Infection Reporting System
MHA Missouri Hospital Association
MoAHQ Missouri Association for Healthcare Quality
MO HEN Missouri Hospital Engagement Network

N

NAHQ National Association for Healthcare Quality
NHSN National Healthcare Safety Network

O

OB obstetrics
OPPE ongoing professional practice evaluation

P

P&T pharmacy & therapeutic
P4P Pay for Performance
PDSA plan, do, study, act
PQRI Physician Quality Reporting Initiative
PSO patient safety organization

Q

QAPI quality assurance/performance improvement
QI quality improvement
QIN Quality Innovation Network
QIO quality improvement organization
QM quality management

R

RCA root cause analysis
RHC rural health clinic

T

TJC The Joint Commission

V
VBP

value-based purchasing